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KAREN GUERRERO			ROYDS, LESLIE A	
25 ROOSTER HILL RD			ART UNIT	PAPER NUMBER
PHOENIXVILLE, PA 19460			1614	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/992,235	LEDERMAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 02 October 2006 and 28 September 2007.  
 2a) This action is **FINAL**.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-8,23 and 24 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 1-8 is/are allowed.  
 6) Claim(s) 23-24 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
     Paper No(s)/Mail Date 06 November 2006.

4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Claims 1-8 and 23-24 are presented for examination.**

Applicant's Amendment filed October 2, 2006 and Supplemental Amendment filed September 28, 2007 to correct the errors in the claim listing as noted in the notice of non-compliant amendment dated September 20, 2007 have each been received and entered into the present application.

Applicant's Information Disclosure Statement (IDS) filed November 6, 2006 has also been received and entered into the present application. However, in view of the fact that Applicant has failed to file the appropriate certification statement under 37 C.F.R. 1.97 or pay the appropriate fee for consideration, the IDS filed November 6, 2006 has not been considered by the Examiner.

Claims 1-8 and 23-24 remain pending and under examination. Claims 23-24 are amended.

Applicant's arguments, filed October 2, 2006 and September 28, 2007, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement***

#### ***(New Grounds of Rejection)***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Present claim 24 is directed to a pharmaceutical composition comprising an effective amount of (R,R'),(R,S')-amphetaminil sulfate or another pharmaceutically acceptable salt thereof for the treatment of a condition benefiting from or requiring a central nervous system stimulant, wherein the composition is substantially free of (S,R'),(S,S')-amphetaminil and further comprises at least one pharmaceutically-acceptable carrier, diluent, excipient or additive, wherein the composition is used, e.g., to potentiate the activity of a conventional antidepressant.

In particular, the specification and claims as originally filed fails to provide adequate written description for the genus of "conventional antidepressants" (claim 24).

MPEP §2163 recites, "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics, coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus." Please reference *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

The instant specification fails to provide any disclosure, either through a limiting definition or even via non-limiting exemplification, of the species of "conventional antidepressants" to be used in combination with the claimed composition of (R,R'),(R,S')-amphetaminil substantially free of the (S,R'),(S,S')-amphetaminil that are encompassed by, and useful for, the presently claimed invention. Disclosure of a representative set of species, relevant identifying characteristics, such as a structure or other physical or chemical properties, or functional characteristics tied to a structural element responsible for said function (i.e., disclosure beyond simply a generic statement of function), that would be sufficient to demonstrate that Applicant was in possession of the entire genus of compounds capable of the functions claimed is conspicuously absent from the specification. Please see *Eli Lilly*, 119 F.3d at 1568,

43 USPQ2d at 1406 and MPEP §2163.

While it is duly noted that the claimed genera of “conventional antidepressants” is clearly limited to those compounds that function as antidepressants, Applicant has failed to clearly define what, in fact, constitutes a “conventional” antidepressant versus a “unconventional antidepressant” such that the skilled artisan would have been reasonably apprised of the metes and bounds of the claimed genus and, thus, what would have constituted a “conventional antidepressant” for use in the instantly claimed invention. Applicant has not appropriately defined the metes and bounds of the genus by providing, for example, (i) a representative set of species of the genus, (ii) a clear definition or indication as to what is meant by the word “conventional” such that one would have been reasonably apprised of the types of antidepressants that would be considered “conventional” and those that would be considered “unconventional” and/or (iii) establishing on the record that the facts of the application (and/or the state of the art) are such that one skilled in the art would have known and, thus, immediately envisaged, what structure or material would, in fact, perform the function(s) recited in the instant claims. The present specification provides no disclosure of any member of the claimed genus of “conventional antidepressants” that would provide a means for identifying these materials amenable for use in the present invention, nor does it teach the specific structure, physical properties or identifying characteristic that constitute a “conventional antidepressant” as recited in the claims. Furthermore, it has been held that a wish or plan for obtaining the chemical invention as claimed does not provide adequate written description of a chemical invention. Rather, a precise definition, such as by structure, formula, chemical name or physical properties, is required. Please reference, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004).

As stated in MPEP §2163, “The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement.” However, considering the teachings provided in the specification as originally filed, Applicant has failed

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to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the genus of "conventional antidepressants" (claim 24).

Accordingly, the claim is considered to lack sufficient written description and is properly rejected under 35 U.S.C. 112, first paragraph.

***Claim Rejections - 35 USC § 112, First Paragraph, Scope of Enablement***

***(New Grounds of Rejection)***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of the claimed pharmaceutical composition for the treatment of a condition or disease selected from narcolepsy, attention deficit hyperactivity disorder, depression, Parkinson's disease, cognitive dysfunction, renal dysfunction, asthma, obesity, nicotine withdrawal, hypotension, apathy, potentiating an opiate for pain control or reduced energy associated with chemotherapy or radiation therapy, does not reasonably provide enablement for the use of the same for treating any disease benefiting from or requiring a central nervous system stimulant, including potentiating the activity of a conventional antidepressant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ 2d 1400 (Fed. Cir. 1988) as to undue experimentation. The factors include:

- 1) the nature of the invention;
- 2) the breadth of the claims;
- 3) the predictability or unpredictability of the art;
- 4) the amount of direction or guidance presented;
- 5) the presence or absence of working examples;
- 6) the quantity of experimentation necessary;
- 7) the state of the prior art; and,
- 8) the relative skill of those skilled in the art.

The relevant factors are addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

The present rejection is also made under the guidance of the MPEP at §2164.01(c), which states, "When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that limitation. See *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991)." Thus, the instant rejection made under 35 U.S.C. 112, first paragraph, is proper as it is applied to the present claims because they are directed to a composition for treating any condition benefiting from or requiring a central nervous system stimulant, such as potentiating the activity of a conventional antidepressant, comprising an effective amount of (R,R'),(R,S')-amphetaminil sulfate or another pharmaceutically acceptable salt thereof.

The presently claimed invention is directed to a pharmaceutical composition comprising an effective amount of (R,R'),(R,S')-amphetaminil sulfate or another pharmaceutically acceptable salt thereof for the treatment of a condition or disease benefiting from or requiring a central nervous system stimulant, where the composition is substantially free of (S,R'),(S,S')-amphetaminil and at least one pharmaceutically acceptable carrier, diluent, excipient or additive. Instant claim 24 further specifies that

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the composition may be used to, e.g., potentiate the activity of a conventional antidepressant.

In particular, one skilled in the art could not practice the presently claimed subject matter without undue experimentation because the artisan would have required adequate guidance as to how to go about effectively using the instantly claimed isomeric amphetaminil composition to potentiate the activity of a conventional antidepressant. Absent any disclosed protocol or guidance by which to accomplish such an objective, the skilled artisan would not have accepted on its face that such a synergistic-type effect (please see Stedman's Medical Dictionary, which defines "potentiation" as "a degree of synergism that is greater than additive"; p.1010) in antidepressant activity could, in fact, have been achieved given the state of the art as discussed below.

As set forth in *In re Marzocchi et al.*, 169 USPQ 367 (CCPA 1971):

"[A] [s]pecification disclosure which contains the teachings of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with the enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contained therein which must be relied on for enabling support*; assuming that sufficient reasons for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in the specification is truly enabling." (emphasis added)

The present claims circumscribe the use of a composition comprising an effective amount of (R,R'),(R,S')-amphetaminil sulfate or another pharmaceutically acceptable salt thereof for the treatment of a condition or disease benefiting from or requiring a central nervous system stimulant, where the composition is substantially free of (S,R'),(S,S')-amphetaminil and contains at least one pharmaceutically acceptable carrier, diluent, excipient or additive, for potentiating the activity of a "conventional" antidepressant. That is, in order to be enabled to practice the present invention, the skilled artisan would

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have to accept that the administration of the claimed composition in combination with a "conventional" antidepressant compound(s) would result in an antidepressant effect that was clearly greater than additive (i.e., synergistic). In view of the fact that the specification not only fails to provide the skilled artisan with any direction or guidance as to how this objective could actually be achieved using the claimed pharmaceutical preparation with a reasonable expectation of success, the present specification is viewed as lacking an enabling disclosure of the entire scope of the invention.

Regarding this use of the claimed composition for potentiating the activity of a conventional antidepressant, the objective truth that such a therapeutic purpose could be effectively achieved is doubted because, while the state of the art with regard to antidepressant therapy is well developed, the state of the art with regard to augmentation therapy using amphetamines in combination with antidepressants is grossly underdeveloped.

In this regard, Little ("Amphetamine, But Not Methylphenidate, Predicts Antidepressant Efficacy", *J Clin Psychopharmacol*, 1988 Jun; 8(3):177-183; Abstract) is cited. Little states that several researchers have explored the possibility that acute stimulant response (i.e., such as that seen with amphetamine) may predict eventual improvement after specific antidepressants. Though Little states that, in five studies, amphetamine responders were found to eventually improve after antidepressant treatment in 85% of the cases, while nonresponders improved in 43% of the cases, Little further discloses that, "The most effective method for administering an amphetamine challenge and its appropriate clinical use remain unclear." Accordingly, Little supports the conclusion that the art was underdeveloped with regard to the significance and manner of effectively executing amphetamine augmentation with a reasonable expectation of achieving a potentiated antidepressant effect.

This is further corroborated by Schweitzer et al. ("A Review of the Use of Augmentation Therapy for the Treatment of Resistant Depression: Implications for the Clinician", *Aust N Z J Psychiatry*. 1997 Jun; 31(3):340-352; Abstract), who discloses that, "There is no empirical evidence supporting buspirone,

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carbamazepine, sodium valproate, methylphenidate or amphetamine as effective augmentation agents, or that adding a tricyclic to a SSRI has usefulness in relieving depressive symptoms. There is a need for considerable research in this area, with more prospective well-controlled placebo studies."

Given the state of the art, which recognized the unpredictability with regard to the effectiveness of amphetamine augmentation therapy with antidepressant therapy to achieve a potentiated antidepressant effect, one of ordinary skill in the art would not accept on its face Applicant's statement that such an objective could be effectively achieved without placing a burden of undue experimentation upon the skilled artisan. The artisan would have required sufficient direction as to how, at minimum, the instantly claimed amphetamine-like composition could have been employed in combination with antidepressant therapy such that the skilled artisan would have been imbued with at least a reasonable expectation of success in actually achieving a synergistic (i.e., potentiated; see Stedman's, citation *supra*) antidepressant effect. Furthermore, such success would not have been reasonably expected in light of what is presently disclosed because the art at the time of the invention failed to recognize this as an effective means of antidepressant augmentation and Applicant has failed to provide any guidance as to how such an objective could actually be achieved. Accordingly, the present specification fails to enable the full scope of this invention as it relates to the objective of using the instant composition for potentiating the activity of a conventional antidepressant and, thus, fails to rebut the presumption of unpredictability in the art with regard to this same objective.

In light of these reasons, it is clear that the present specification fails to provide adequate guidance as to how one skilled in the art would accomplish the objective of potentiating the activity of a conventional antidepressant such that a synergistic antidepressant effect would have been achieved, given what is disclosed in the present specification. Applicant fails to provide any working example(s) of how the presently claimed composition could be used and/or administered such that the instantly claimed objective of potentiating the activity of a conventional antidepressant could actually be effectively

accomplished.

While the lack of a working embodiment cannot be the sole factor in determining enablement, the absence of substantial evidence commensurate in scope with the presently claimed subject matter, in light of the unpredictable nature of the art and the direction (or lack thereof) that Applicant has presented, provides additional weight to the present conclusion of insufficient enablement in consideration of the *Wands* factors as a whole. The instant specification conspicuously lacks any disclosure or teaching of manner and process of how the instantly claimed composition could be employed such that the activity of an antidepressant compound could be effectively potentiated to achieve a synergistic antidepressant effect and, further, that the skilled artisan would have been imbued with at least a reasonable expectation of success in actually achieving such an objective without the burden of an undue level of experimentation. For these reasons, Applicant has failed to obviate the presumption of unpredictability in the art.

As stated in MPEP §2164.04[R-1], "Doubt may arise about enablement because information is missing about one or more essential parts or relationships between parts which one skilled in the art could not develop without undue experimentation." In the instant case, the information that is missing is a clear description of a manner of using the presently claimed amphetaminil composition in combination with a conventional antidepressant such that the skilled artisan would have had a reasonable expectation of success in actually achieving a potentiated antidepressant effect when the two compounds were used together, particularly because the state of the art at the time of the invention was such that it did not recognize such an objective as sufficiently predictable and/or effective. Furthermore, in the absence of any evidence supporting the allegation that the claimed compound is, in fact, effective to achieve such a therapeutic objective, either by reduction to practice or at least by elucidating the mechanism by which the claimed compound works to correlate its activity to the expectation of augmenting (or potentiating) the function of an antidepressant when combined, the specification fails to provide adequate guidance and/or direction to one of skill in the art at the time of the invention that would have enabled the artisan to

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practice the instantly claimed invention without having to resort to undue experimentation to determine how one would achieve the instantly claimed objective.

The basis for the present rejection is not simply that experimentation would be required, since it is clear from the state of the prior art and Applicant's disclosure and remarks that experimentation in this particular art is not at all uncommon, but that the experimentation required in order to practice the full scope of the invention would be *undue*. Please reference *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976), which states, "The test of enablement is not whether any experimentation is necessary, but whether, *if experimentation is necessary, it is undue*." (emphasis added) Accordingly, in the absence of any adequate disclosure, direction or guidance as to how one would go about using such compounds for the full scope of conditions and/or diseases claimed with a reasonable expectation of successfully treating the claimed disorder, it remains that the pharmaceutical, chemical and medical arts are notoriously complex such that the specific uses of a particular pharmaceutical composition would have been sufficiently unpredictable to warrant the need for undue experimentation to actually practice the full scope of the invention as instantly claimed.

In view of the discussion of each of the preceding seven factors, the level of skill in the art is high and is at least that of a medical doctor or scientist with several years of experience in the art.

As the cited art and discussion of the above factors establish, practicing the claimed method in the manner disclosed by Applicant would not imbue the skilled artisan with a reasonable expectation or ability to make and use the full scope of the invention as instantly claimed, given the disclosure and supporting examples provided in the present specification and the state of the art at the time of the invention. In order to actually achieve the claimed invention, it is clear from the discussion above that the skilled artisan could not rely upon Applicant's disclosure as required by 35 U.S.C. 112, first paragraph, and would have no alternative recourse but the impermissible burden of undue experimentation in order to practice the full scope of the embodiments presently claimed.

***Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Present claim 24 is directed to a pharmaceutical composition comprising an effective amount of (R,R'),(R,S')-amphetaminil sulfate or another pharmaceutically acceptable salt thereof for the treatment of a condition benefiting from or requiring a central nervous system stimulant, wherein the composition is substantially free of (S,R'),(S,S')-amphetaminil and contains at least one pharmaceutically-acceptable carrier, diluent, excipient or additive, wherein the composition is used, e.g., to potentiate the activity of a conventional antidepressant.

In particular, the claims fail to clearly, precisely or deliberately set forth what, in fact, constitutes a "conventional" antidepressant and what constitutes an "unconventional" antidepressant such that the skilled artisan would have been reasonably apprised of the metes and bounds of what antidepressant compounds would actually infringe the instant claims. Absent such disclosure, the skilled artisan would not have been reasonably apprised as to what specific antidepressant compounds would be tolerated by the instant claims. Moreover, the term "conventional" is specifically related to what is traditional or usual at a particular point in time and, thus, is reasonably expected to change over time such that what may be "conventional" at one time in the art may not necessarily be considered "conventional" at another point in time in the art. Accordingly, clarification of the phrase "conventional antidepressant" is requested.

For these reasons, the claim fails to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and is, thus, properly rejected.

*Conclusion*

The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. Please reference the publications to Nencini et al. ["(-)-Norpseudoephedrine, A Metabolite of Cathinone with Amphetamine-Like Stimulus Properties, Enhances the Analgesic and Rate Decreasing Effects of Morphine, But Inhibits its Discriminative Properties". *Behavioral Brain Research*. 92; 1998:11-20] and Izenwasser et al. ("Potentiation of Morphine Analgesia by D-Amphetamine is Mediated by Norepinephrine and Not Dopamine". *Pain*. 1988 Jun; 33(3):363-368; Abstract Only).

Rejection of claims 23-24 remains proper and is maintained.

Claims 1-8 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

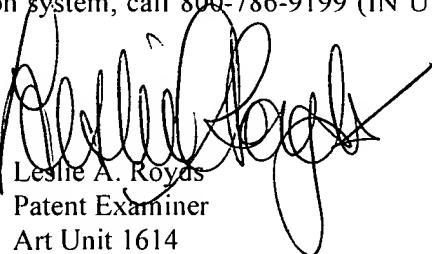
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie A. Royds  
Patent Examiner  
Art Unit 1614

December 20, 2007

*Frederick Krass*  
*Primary Examiner*  
*Art Unit 1614*  
*[Signature]*